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Guidance for Industry

Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims

This guidance provides advice to industry regarding the procedures that the Center for Veterinary Medicine (CVM) intends to use to grant Expedited Review Status for applications for new animal drugs intended to reduce human pathogens in animals.

Comments and suggestions regarding this document should be sent to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 01D-0107.

For questions regarding this document, contact Dr. Steven Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7580, E-mail: svaughn@cvm.fda.gov.

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Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims

This guidance provides advice to industry regarding the procedures that CVM intends to use to grant Expedited Review Status for applications for new animal drugs intended to reduce human pathogens in food-producing animals. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Purpose of this guidance:

   FDA believes it is in the interest of public health to grant Expedited Review Status (ERS) to applications for new animal drugs that may decrease the incidence of human illness through their action against human pathogens in animals and that meet the criteria in this guidance.

   This guidance provides procedures for requesting and criteria for granting ERS to new animal drug applications (NADAs) submitted to the Agency for approval of new animal drugs for which the label would bear human pathogen reduction claims. Under CVM's expedited review program, such products that potentially offer important advances in human pathogen reduction in food-animals should receive expedited review commencing at the Investigational New Animal Drug (INAD) stage. ERS does not affect the approval standard; applications are expected to meet the same standards for data quality and evaluation that apply for other new animal drug approvals.

   For products that may be considered to be important advances in animal health (rather than in human pathogen reduction), see CVM's Program Policy and Procedures Manual Guide 1240.3135, entitled "Animal Drug Applications Expedited Review Guideline."

2. Background:

   Under the expedited review program, submissions under an INAD or NADA to support approval of an application for a new animal drug that meet the criteria for ERS should receive a higher priority for review and a faster review than routine applications receive. If the proposed drug product meets the criteria for ERS outlined in this guidance, then the sponsor may request that CVM give the drug ERS.

3. Criteria:

   ERS should be granted under this guidance if (1) the new animal drug is intended to produce a biologically significant and quantifiable reduction of a human

pathogen in the indicated animal species and (2) the effect is measurable at the probable point of intervention. For example:

(a) If the effect is on recognized food-borne pathogens, the effect should be measurable when the animals are presented for slaughter.

(b) If the disease is transmitted directly or through an intermediate host to humans and is not a recognized food-borne pathogen, the effect should be measurable when the disease is likely to be transmitted to the human population. At a minimum, this effect should be to reduce the risk of exposure to a disease pathogen in humans.

Expedited review status should be granted for an application for the new animal drug even if there is a similar new animal drug approved for the same intended use or that causes a similar human pathogen reduction benefit by a similar mechanism of action. An application for a new use of a new animal drug that is already the subject of an approved new animal drug application for any use in the same species should not be granted expedited review status because it does not represent an important advance in human pathogen reduction.

4. Procedures:

a. Timing.

(1) ERS should be requested as early as possible in the drug development and review process.

(2) ERS should be requested after an INAD has been established, but before the new animal drug application is approved.

(3) In the absence of a sponsor's request for ERS, the Director, Office of New Animal Drug Evaluation (ONADE) (HFV-100) should, at any time after an INAD has been established and before the new animal drug application is approved, determine whether an INAD/NADA qualifies for ERS. If the Center grants ERS, CVM should notify the sponsor.

b. How to request ERS.

The sponsor should submit to the appropriate Division Director in the ONADE, CVM, a written request for review under the expedited review program. The request should identify the sponsor and the sponsor's address and should reference information in the sponsor's INAD file that demonstrates that the new animal drug application is eligible for ERS. Referenced information should demonstrate convincingly that the new animal drug can reasonably be expected to have the intended human

pathogen reduction effect. Regardless of whether an NADA is granted ERS, CVM will not approve an application for a new animal drug unless the application includes information to demonstrate that the new animal drug is safe and effective for its proposed uses (21 U.S.C. 360b(d)(1)).

c. Granting ERS.

The Division assigned the application and the Director of ONADE should make the decision whether to grant ERS. CVM may assign ERS to an INAD or NADA any time prior to the approval of the new animal drug. CVM should inform the sponsor of its decision to grant ERS within 60 days of CVM's receipt of the request.

d. Withdrawal of ERS.

CVM should withdraw ERS status of an INAD or NADA if:

(1) the sponsor does not show due diligence in pursuing the approval of the new animal drug or responding to CVM correspondence, or

(2) data and other information are submitted or otherwise become available indicating that the new animal drug does not provide a significant human pathogen reduction benefit.

If ERS is withdrawn, the Director of ONADE should notify the sponsor, and any pending application should be handled under standard, non-ERS procedures.